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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|----------------------------|---------------|----------------------|-------------------------|------------------|--|
| 09/594,065 | 06/14/2000 | Cindy WalkerPeach | 25436/1280 | 7768 | |
| 27495 75 | 90 10/01/2003 | | EXAMINER | | |
| PALMER & DODGE, LLP | | | SCHEINER, LAURIE A | | |
| KATHLEEN M. WILLIAMS / STR | | | ART UNIT | PAPER NUMBER | |
| BOSTON, MA | | | 1648 | | |
| | | | DATE MAILED: 10/01/2003 | 11 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/594,065

Applicant(s)

Walker Peach et al.

Examiner

Laurie Scheiner

1648



| | The MAILING DATE of this communication appears of | on the cover sh ϵ | et with | the correspondence address | | | |
|---|--|--|------------------------|---|--|--|--|
| | for Reply | | | l | | | |
| | ORTENED STATUTORY PERIOD FOR REPLY IS SET T MAILING DATE OF THIS COMMUNICATION. | TO EXPIRE | _3 | _ MONTH(S) FROM | | | |
| | - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. | | | | | | |
| - If the p - If NO p - Failure - Any re | grated of this communication. period for reply specified above, the maximum statutory period will apply as to reply within the period for reply is specified above, the maximum statutory period will apply as to reply within the set or extended period for reply will, by statute, cause the ply received by the Office later than three months after the mailing date of the period term adjustment. See 37 CFR 1.704(b). | and will expire SIX (6) the application to become | MONTHS fr me ABANDO | from the mailing date of this communication. ONED (35 U.S.C. § 133). | | | |
| Status | | | | l | | | |
| 1) 💢 | Responsive to communication(s) filed on Sep 2, 200 | 03 | | · | | | |
| 2a) 🗆 | This action is FINAL . 2b) ✓ This action | ion is non-final. | | l l | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | | | | | |
| - | tion of Claims | | | l | | | |
| 4) 💢 | Claim(s) 1-34 | | | is/are pending in the application. | | | |
| 4 | 4a) Of the above, claim(s) <u>1, 2, 11-16, and 23-34</u> | | | is/are withdrawn from consideration. | | | |
| 5) 💢 | Claim(s) 6-9 and 17-22 | | | is/are allowed. Fizee of the | | | |
| | Claim(s) 3-5 and 10 | | | | | | |
| 7) 💢 | Claim(s) <u>11 and 13</u> | | | is/are objected to. | | | |
| 8) 🗆 | Claims | are | subject | to restriction and/or election requirement. | | | |
| Applica | ation Papers | | | ļ , | | | |
| 9) 🗆 | 9) The specification is objected to by the Examiner. | | | | | | |
| 10) | 10)□ The drawing(s) filed on is/are a)□ accepted or b)□ objected to by the Examiner. | | | | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11) | The proposed drawing correction filed on | is: | a)□ <i>a</i> | approved b) \square disapproved by the Examiner. | | | |
| | If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) | 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| | a) □ All b) □ Some * c) □ None of: | | | | | | |
| | 1. La Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No. | | | | | | |
| Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) | | | | | | | |
| ,, <u></u> a} [| | | | | | | |
| 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachm | | P , 1 | | 3. 3. 1. 3. 3. 3. 3. 3. 3. 3. 3 | | | |
| 1) No | otice of References Cited (PTO-892) | 4) Interview Sur | nmary (PTC | O-413) Paper No(s) | | | |
| 2) No | otice of Draftsperson's Patent Drawing Review (PTO-948) | 5) Notice of Informal Patent Application (PTO-152) | | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) Other: | | | | | | | |

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Claims 1-34 are pending in this application. Applicant's election of claims 3-22, in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1, 2 and 23-34 are withdrawn from consideration.

Claims 11 and 13 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. Claim 11 also depends from a non-elected claim. Claims 12-16 depend, or ultimately depend, from non-elected claim 2 and therefore will not be examined.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 3-5 and 10 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The DNA, as claimed, has the same characteristics and utility as that found in nature and therefore does not constitute patentable subject matter. In the absence of the hand of man, the naturally occurring polynucleotide is considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co., 283 US 1 (1931); Funk Brother Seed Co. v. Kalo Inoculant Co., 283 US 127 (1984). Amending

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the claims to recite a purity limitation is suggested to obviate this rejection. Suggested language is "An isolated polynucleotide for HSV detecting. . . "

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.

Laurie Scheiner/LAS September 19, 2003

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